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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,505	06/28/2001	Saluh Kivlighn	50193-109	4997

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EXAMINER
NGUYEN, QUANG

ART UNIT	PAPER NUMBER
1636	3

DATE MAILED: 09/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/892,505	KIVLIGHN ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-13 are pending in the present application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group Restriction:

I. Claims 1-2 and 5-9, drawn to methods of treating and preventing hypertension comprising administering a therapeutically effective amount of an agent, and an agent capable of reducing uric acid levels, classified at least in class 514, subclass 44; class 424, subclass 94.1 for examples, depending on the nature of the agent.

II. Claims 3 and 5-9, drawn to methods of treating coronary heart disease comprising administering a therapeutically effective amount of an agent, and an agent capable of reducing uric acid levels, classified at least in class 514, subclass 44; class 424, subclass 94.1 for examples, depending on the nature of the agent.

III. Claims 4 and 5-9, drawn to methods of treating and preventing eclampsia comprising administering a therapeutically effective amount of an agent, and an agent capable of reducing uric acid levels, classified at least in class 514, subclass 44; class 424, subclass 94.1 for examples, depending on the nature of the agent.

IV. Claims 10-13, drawn to a pharmaceutical composition comprising a rennin angiotensin system (RAS) inhibitor, or pharmaceutically acceptable salt thereof and the agent capable of reducing uric acid levels, and a combination therapy comprising the administration, concomitantly, simultaneously or sequentially, of therapeutically effective amounts of the same pharmaceutical composition can not be classified because the structure of a RAS inhibitor is not recited in the claims.

Should one of the Groups I-IV be elected, **further group restriction is required** because the claims in each Group contain patentably distinct agents capable of reducing uric acid levels that lack the unity of invention. The agents capable of reducing uric acid levels encompassed by the presently claimed invention (e.g., gene therapy, a xanthine oxidase inhibitor, a uricosuric agent, supplements of the uricase protein and a urate channel inhibitor) do not share a substantial common core structure or element among themselves. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. Thus, claims 1-5 and 10-13 link a multiple distinct inventions. The restriction requirement between linked inventions is subject to the non-allowance of the linking claims 1-5 and 10-13. The restriction requirement between linked inventions is subject to the non-allowance of the linking claim(s), 1-5 and 10-13.

Applicant is required under 35 U.S. C 121 to elect a specific agent comprising: (a) a gene therapy (without reciting any structure); (b) a xanthine oxidase inhibitor; (c) a

uricosuric agent; (d) supplements of the uricase protein; and (e) a urate channel inhibitor.

Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-132(CCPA 1971). See also MPEP 804.01.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-IV differ one from the others because the method of treating and preventing hypertension of Group I, the method of treating coronary heart disease of Group II, and the method of treating and preventing eclampsia of Group III differ one from the others of the starting materials (e.g., patients having specific diseases such as hypertension, coronary heart disease and eclampsia), different desired treatment results for the distinct diseases and therefore they require different technical considerations. The pharmaceutical composition of Group IV is not required for the practice of any of the methods of Groups I-III as evidenced by the absence of a

need for the utilization of a RAS inhibitor. Similarly, the pharmaceutical composition of Group IV is distinct from the utilized agent in any of the Groups I to III by the presence of RAS inhibitor.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and separate search requirements, it would be unduly burdensome for the examiner to search and/or consider the patentability of all the inventions in one application. Therefore, restriction for examination purposes as indicated is proper.

Species Restriction:

Should Applicants elect any of the inventions of Groups I-IV, and xanithine oxidase inhibitor as a separate agent group, claims directed to the following patentably distinct species:

Claims 1-5, 7 and 10-13 are generic to a plurality of disclosed patentably distinct species comprising: (a) allopurinol; and (b) carprofen.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Should Applicants elect any of the inventions of Groups I-IV, and uricosuric agent as a separate agent group, claims directed to the following patentably distinct species:

Claims 1-5, 8 and 10-13 are generic to a plurality of disclosed patentably distinct species comprising: (a) losartan; (b) benzbromarone; (c) benziodarone; (d) probenecid; (e) sulfinpyrazone; (f) ethebencid; (g) orotic acid; (h) ticrynafen; and (i) zoxazolamine.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by

a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Dave Nguyen, may be reached at (703) 305-2024, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636.

Quang Nguyen, Ph.D.

DAVE T. NGUYEN
PRIMARY EXAMINER